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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,386	04/14/2004	Mordechay HersHKovitz	1662/63402	8459

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EXAMINER

DAVIS, BRIAN J

ART UNIT PAPER NUMBER

1621

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/825,386

Applicant(s)

HERSHKOVITZ ET AL.

Examiner

Brian J. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 61, 62, 66-69, 71, 72, 74 and 75 is/are allowed.
- 6) ☒ Claim(s) 1-60, 63, 65, 70, 73 and 76-87 is/are rejected.
- 7) ☒ Claim(s) 20, 33, 50, 64 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/14/05</u> . | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Claim Objections

Claims 20, 33 and 50 are objected to because of the following informalities: the claims contain obvious grammatical errors. With respect to claim 20, the article "the" should appear before the word ratio. With respect to claims 33 and 50, the word "of" should be deleted. Appropriate correction is required. Applicant's assistance is respectfully requested in correcting any other minor grammatical and or/spelling errors that may be present in the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 23 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear, in a process for preparing sertraline, how it could be optional to actually make sertraline (converting the...compound to sertraline *if necessary* [emphasis added]).

Claims 8, 25 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear, in light of the prior art, if

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applicant truly wishes to exclude compounds when the oxygen atom has a substituent as the claims presently read, or if applicant instead wishes to exclude Y altogether.

Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The significance of dividing a continuous range of mesh sizes into two sequential groups is unclear. That is, isn't the range of mesh sizes simply about 30 to about 80 mesh?

The remaining claims up to claim 60 are also rejected under 35 USC 112, second paragraph, as claims which depend from indefinite claims are also indefinite. *Ex parte Cordova*, 10 USPQ 2d 1949, 1952 (PTO Bd. App. 1989).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22, 42, 60, 65, 70, 73 and 78 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by *The Merck Index* 12th edition, entry number 8612. The instant claims are product-by-process claims and even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious

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from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) MPEP 2112.02. Sertraline is an old and well-known compound used in pharmaceutical compositions for many years, as evidenced by the cited reference.

Claims 76 and 77 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by *The Merck Index* 12th edition, entry number 8612. There are a number of decisions holding that where the purification of an old product results in a mere change in degree in its properties, the purified form is unpatentable. *Ex parte Windhaus*, 15 USPQ 45 (POBA 1931); *In re Ridgeway*, 76 F.2d 602, 25 USPQ 202 (CCPA 1935); *In re Mertz*, 97 F.2d 599, 38 USPQ 143 (CCPA 1938); *In re Macallum*, 102 F.2d 614, 41 USPQ 146 (CCPA 1939); *In re King*, 107 F.2d 614, 43 USPQ 400 (CCPA 1939); *Ex parte Sparhawk*, 64 USPQ 339 (POBA 1945); *In re Weijlard*, 154 F.2d 133, 69 USPQ 86 (CCPA 1946); *In re Johnson*, 94 F.2d 978, 37 USPQ 75 (CCPA 1938); *Ex parte Cavillito*, 89 USPQ 449 (POBA 1950); *Ex parte Snell*, 86 USPQ 496 (POBA 1950); *In re Fisher*, 307, F.2d 948, 135 USPQ 22 (CCPA 1962); *Ex parte Hartop*, 139 USPQ 525 (POBA 1962); *Ex parte Siddiqui*, 156 USPQ 426 (POBA 1966); *Ex parte Schmidt-Kastner*, 153 USPQ 473 (POBA 1963). The cited reference teaches applicant's compound.

Claim 87 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by *Applied Catalysis A: General*, 79 (1991), page 167-180. As above, the instant claim is a product-by-process claim and even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself.

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The cited reference teaches Co/ silica-alumina catalysts prepared by impregnation followed by drying and calcination (abstract; page 169 Experimental section).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,536,518, cited by applicant in the IDS.

Applicant claims a hydrogenation process of the compound diagramed in the claim using a metal catalyst in a trickle bed reactor.

US 4,536,518 teaches the batch hydrogenation of applicant's compound using Pd/C (column 10 line 11).

Applicant distinguishes over the prior art in that a particular reactor type is taught. However, case law is clear on this point: The mere selection of reaction vessel cannot impart patentability, there can be no invention even though the results are better. *In re Leum et al.*, 158 F.2d 311, 597, 72 USPQ 127 (CCPA1947).

Claims 23-41 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,034,274.

Applicant claims a hydrogenation process of the compound diagramed in the claim using a metal catalyst in a trickle bed reactor. The dependent claims further refine the process.

US 6,034,274 teaches the batch hydrogenation of applicant's compound using Raney-Nickel (column 2 line 43; Experimental).

The key to the instant invention is the trickle bed reactor. However, as above, the mere selection of reaction vessel cannot impart patentability, there can be no invention even though the results are better. The dependent claims represent mere

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engineering expediencies – absent some unexpected result. The adjustment of temperatures, pressures, flow rates, etc. in order to optimize a given process are all part and parcel of routine laboratory experimentation. This is supported by case law: Merely modifying process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality. *In re Aller*, 220 F.2d 454, 105 USPQ 233 (CCPA 1955). Likewise, selection of particle size is not a patentable modification in the absence of unobvious results. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claims 79-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2,486,361 and further in view of US 3,860,532.

Applicant claims a process for preparing a cobalt catalyst (claim 79). The dependent claims further refine the process.

US 2,486,361 teaches the preparation of impregnated heterogeneous catalysts (column 2 line 5).

US 3,860,532 teaches the preparation of silica-alumina catalysts (abstract).

Applicant's process is an old and well-known process for the preparation of impregnated heterogeneous catalysts. This is evidenced by US 2,486,361 which teaches the preparation of such catalysts by the impregnation of a carrier in the form of granules or pellets by immersion in a solution of the desired metal salt (cobalt nitrate is explicitly taught) where the impregnated carrier is then dried and calcined in order to convert the adsorbed metal to its oxide (column 2 line 5; Examples). The above

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impregnation technique is widely known and has been used in the art for decades because it has several advantages, not the least of which is economic (column 3 line 2).

It works with any number of carriers: alumina, silica, zirconia, thoria, magnesia, magnesium hydroxide, titania, *or any combination of these* [emphasis added] i.e. silica-alumina (column 7 line 2). *Many* [emphasis added] modifications of the impregnation procedure are explicitly contemplated (column 9 line 35). This is so because the reference is a general reference giving guidelines for a widely applicable technique.

One such obvious modification is evidenced by US 3,860,532 which teaches the calcinations of a silica-alumina carrier for use as a catalytic support before impregnation (abstract; column 3 line 3). One of ordinary skill in the art would be motivated to make such a modification to the carrier in order to benefit from the catalyst's increased strength and activity (column 5 line 42).

The dependent claims are included in this rejection as they represent mere engineering expediences - absent some unexpected result. The adjustment of temperatures, pressures, flow rates, etc. in order to optimize a given process are all part and parcel of routine laboratory experimentation. This is supported by case law: Merely modifying process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality. *In re Aller*, 220 F.2d 454, 105 USPQ 233 (CCPA 1955).

Allowable Subject Matter

Claims 61, 62, 66-69, 71, 72, 74 and 75 are allowed. Claims 1-21 and 43-59 would be allowable once the 112, second paragraph, rejection outlined above has been overcome. Claim 64 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter:

The key to the instant invention is the catalyst, either Co or supported Ni. The closest prior art appears to be US 4,536,518, cited by applicant in the IDS, and US 6,232,501 B1. US 4,536,518 teaches the instant reduction using a Pd/C catalyst (column 10 line 11) while US 6,232,501 B1 teaches using a Cu catalysts (column 7 line 33). The cited prior art neither teaches nor suggests the instant catalysts. Nor would it have been obvious to one of ordinary skill in the art at the time of invention to modify the processes of the prior art in order to arrive at that of the instant invention. There is no motivation to do so.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 **BRIAN DAVIS**
PRIMARY EXAMINER

Brian J. Davis
October 5, 2005